Nuclear Regulatory Commission's Quality Assurance Criteria

Internal Control Model for Technology Operations

Jeffrey C. Worthington, CQA, CQMgr.
OEI Director of Quality
Management Integrity Advisor
Office of Environmental Information
U.S. Environmental Protection Agency

Fellow
Past-Chair, Energy and Environmental Division
American Society for Quality

DOD Environmental Monitoring and Data Quality Workshop
Arlington, Virginia
March 28th - April 1st 2011

Report Documentation Page

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
31 MAR 2011		**00-00-2011 to 00-00-2011**

4. TITLE AND SUBTITLE	5a. CONTRACT NUMBER
Internal Control Model for Technology Operations	5b. GRANT NUMBER
	5c. PROGRAM ELEMENT NUMBER
6. AUTHOR(S)	5d. PROJECT NUMBER
	5e. TASK NUMBER
	5f. WORK UNIT NUMBER
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) **U.S. Environmental Protection Agency,Office of Environmental Information,1200 Pennsylvania Ave, N.W.,Washington,DC,20460**	8. PERFORMING ORGANIZATION REPORT NUMBER
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)	10. SPONSOR/MONITOR'S ACRONYM(S)
	11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION/AVAILABILITY STATEMENT
Approved for public release; distribution unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

15. SUBJECT TERMS

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			
unclassified	**unclassified**	**unclassified**	**Same as Report (SAR)**	**31**	

Jeffrey Worthington- BIO

- Director of Quality for the USEPA Office of Environmental Information. Jeff served as the Director of Quality USEPA ORD National Risk Management Research Laboratory (NRMRL) and as the Director of Quality Assurance for TechLaw, Inc. He is an American Society for Quality (ASQ) Certified Quality Manager and ASQ Certified Quality Auditor. Jeff is an elected ASQ Fellow, a founding member of the Government Division, Past-Chair of the ASQ Energy & Environment Division, and a past member of the ASQ Division Affairs Council. He is a founding member and past Director of the International Association for Information and Data Quality (IAIDQ). Jeff served as Editorial Board member for Quality Assurance, Science, and the Law, the Journal of Environmental Forensics, Environmental Laboratory magazine, and Environmental Testing and Analysis magazine.

- As a Federal Government since 1994. Jeff co-led a team authoring the combined quality and management system for EPA's Environmental Technology Verification (ETV) program. He co-led the EPA team developing EPA's Information Quality Guidelines. Jeff co-authored peer review journal papers receiving 1)the USEPA Science and Technological Achievement Award (STAA), Level III for equating EPA policies and procedures to U.S. Supreme Court Sound Science Criteria (2002) and 2)an STAA Honorable Mention for developing electronic recordkeeping QA parameters (2006).

- National Security Telecommunications and Information Systems Security (NSTISSI) 4011 Certificate for information systems security (INFOSEC) professionals and a Chief Information Officer (CIO) certificate from the National Defense University (NDU) Information Resources Management College (IRMC).

- Jeff served as a Peace Corps Volunteer in Kpandu, Ghana from 1977-1979.

Peace Corps - 50th Anniversary

History

- Peace Corps officially established: March 1, 1961
- Total number of Volunteers and trainees to date: 200,000+
- Total number of countries served: 139

Information

- 50th Anniversary - http://www.peacecorps.gov/index.cfm?shell=about.fiftieth
- "Peace Corps Volunteer Ghana 1977" http://www.facebook.com/pages/Peace-Corps-Volunteer-Ghana-1977/184669711550989#!/pages/Peace-Corps-Volunteer-Ghana-1977/184669711550989?sk=photos

DISCLAIMER

The opinions expressed in this technical presentation are those of the authors and do not necessarily reflect the views of the US EPA.

OVERVIEW

- First the basics!
- 1990's What was the basis for DOE quality requirements?
- 1994 Why did DOE and EPA "harmonize" quality requirements?
- Where does quality fit into NRC's regulatory model?
- What are the nuclear requirements?
- What are the needs for environmental technology and environmental measurement quality?
- Can the nuclear approach be used?
- New questions?

Internal Control - basics

Internal control is an integral component of an organization's management that provides reasonable assurance that the following objectives are being achieved:

- effectiveness and efficiency of operations, (for example, a quality control)
- reliability of financial reporting, and
- compliance with applicable laws and regulations.

Quality basics

- Based on scientific method
- Plan-do-check-act = hypothesize, experiment, test, and improve
- “First” used by engineers

“Engineering” quality basics

Usually focused on a hardware solution – an “engineered” tangible product

- Planning
- Design
- Construction
- Installation

"environmental measurement" quality basics

Focus on measurements of natural systems – chemical, physical, biological, geographical (x-y-z), population

- Measurement planning
- Sampling
- Analysis
- Data review
- (decision)

1990's What was the basis for DOE quality requirements?

- NQA – 1 used in DOE community to accomplish nuclear requirements

- ASQ Energy Division – Nuclear Quality Systems Auditor Training Manual (based on NQA-1)

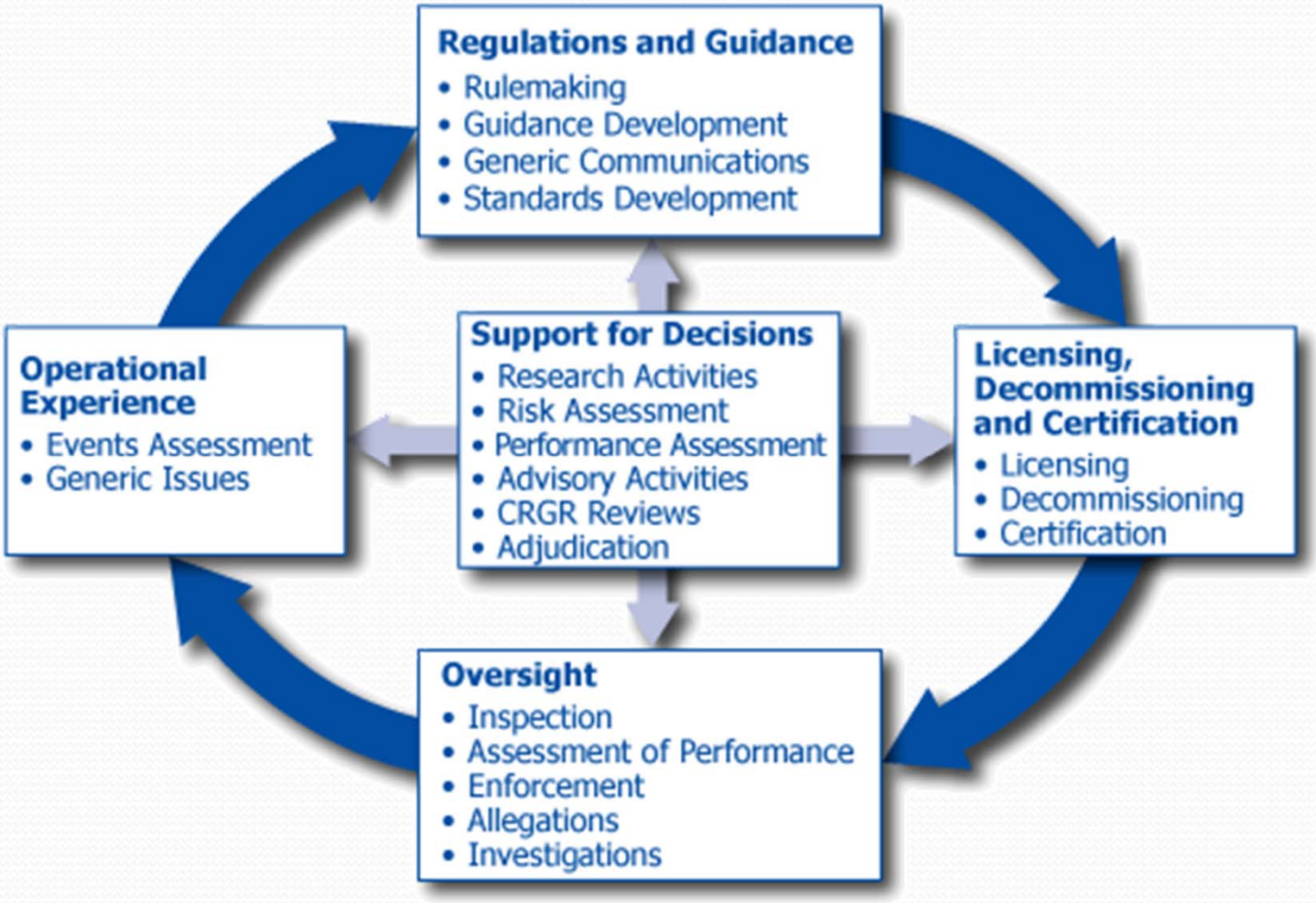
Why did DOE and EPA "harmonize" quality requirements?

- Focus on DOE sites:
  - Environmental monitoring
  - Cleanup plans
  - DOE laboratories to conduct environmental analysis
- Quality requirements currently available
  - NQA – 1 – focus on engineering needs
  - EPA QAMS – focus on environmental measurements
- ASQ Energy Division became ASQ Energy & Environment Division

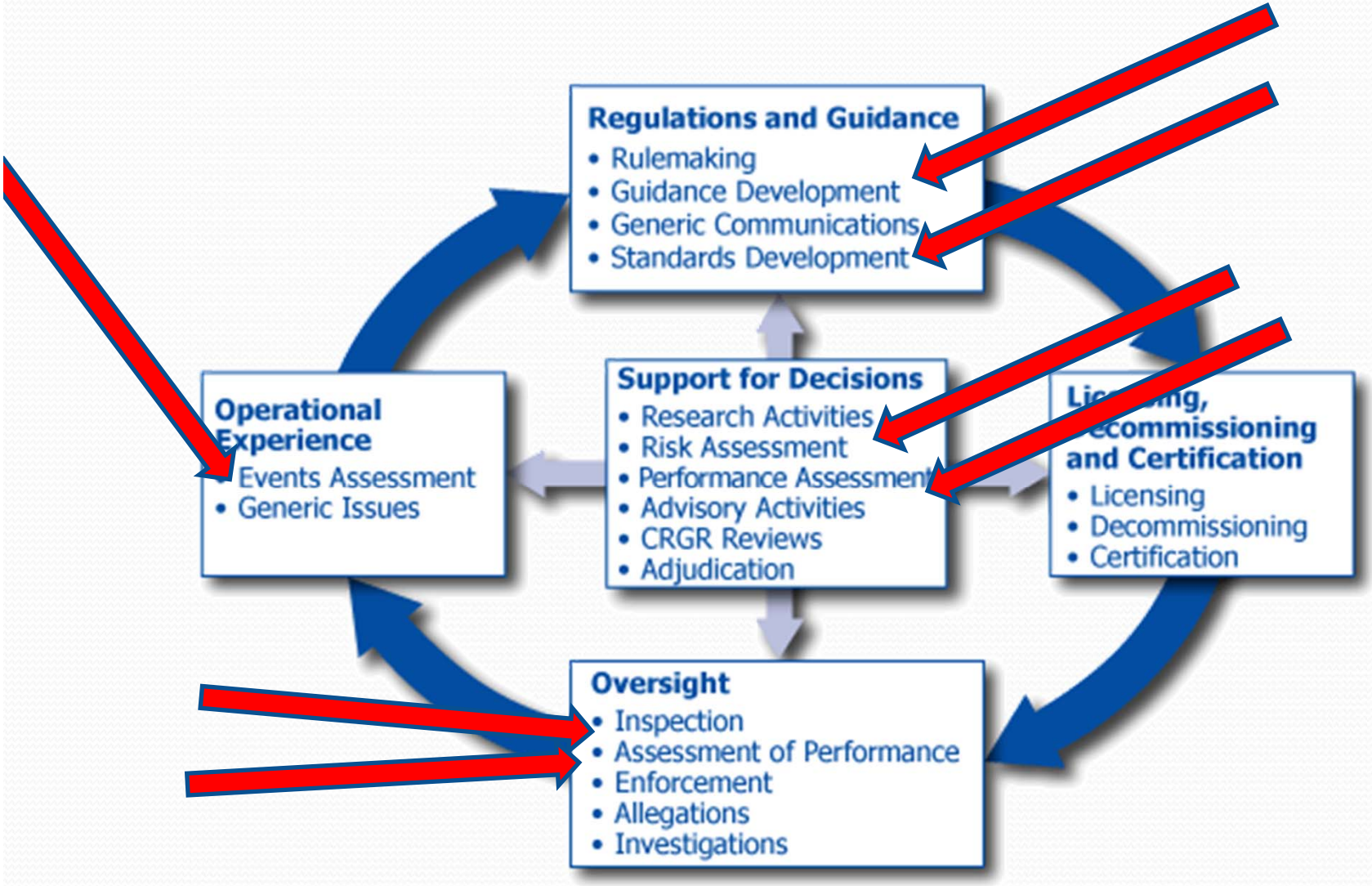
What did E-4 accomplish?

- Aligned nuclear (engineering) and environmental quality programs
- Recognized need for environmental scientists to apply quality practices to environmental technology
- Provided more structured guide for measurement planning in combined science and engineering applications
- Highlighted general lack of guidance for applying quality planning to environmental technology
- Introduced concept of planning for (environmental) quality associated with information hardware and software
- Served as the basis for a new EPA quality system based on E-4
- Provided the basis for further development of quality guidelines and procedures

NRC's "How We Regulate"
http://www.nrc.gov/about-nrc/regulatory.html



Where does quality fit into NRC's Regulatory Model?



The NRC Approach - Documents

- Code of Federal Regulations (CFR)
  - Appendix B to 10 CFR Part 50
- NUREG – publications prepared by NRC staff
  - NUREG/BR = brochures prepared by the NRC Staff
  - NUREG/CP = conference proceedings prepared by NRC Staff or Contractors
  - NUREG/CR = conference proceedings prepared by NRC Contractors
  - NUREG/IA = publications resulting from international agreements
  - STS = Standard Technical Specification – a collection of NUREG documents for each major type of engineering plant
    - TSTF = Technical Specification Task Force "travelers,".... Travelers are a process used to initiate changes to the STS. Additional details are available in the endnote.
    - CLIIP = Consolidated Line Item Improvement Process – this is a method to streamline license amendment review process involving TSTF changes
    - Risk Management Technical Specifications – risk-informed improvements to technical specifications are made using PRA = probabilistic risk assessment
- Regulatory Guides
- Office of New Reactors
  - ITAAC = inspections, tests, analyses, and acceptance criteria

10 CFR Domestic Licensing of Production and Utilization Facilities

Part	Subject
Appendix A to 10 CFR Part 50	General Design Criteria
Appendix B to 10 CFR Part 50	Main QA Regulation
10 CFR Part 21	Reporting of Defects and Noncompliance (Last updated December 1, 2009)
10 CFR 50.4(b)(7)	Written Communications - Quality Assurance Related Submittals
10 CFR 50.34(b)(6)(ii)	QA Program Description
10 CFR 50.34(f)(3)(ii) and 10 CFR 50.34(f)(3)(iii)	Requirements Related to the Incident at Three Mile Island (TMI) (I.F.1 and I.F.2)
10 CFR 50.36(c)(5)	Administrative Controls
10 CFR 50.54(a)(1)	QA Program Requirement
10 CFR 50.54(a)(2)	Submittal of QA Program Description
10 CFR 50.54(a)(3)	QA Program Description Change Control
10 CFR 50.54(a)(4)	Reductions in Commitments in QA Program
10 CFR 50.55(e)	Evaluation of Defects and Failures To Comply Associated with a Substantial Safety Hazard
10 CFR 50.55a	Codes and Standards
10 CFR 50.71(e)	Maintenance of Records
10 CFR 52.17(a)(xi)	QA Program Description (Early Site Permits)
10 CFR 52.47(a)(8)	TMI-Related Requirements (Design Certifications)
10 CFR 52.47(a)(19)	QA Program Description (Design Certifications)
10 CFR 52.79(a)(17)	TMI-Related Requirements (Combined Licenses)
10 CFR 52.79(a)(25)	QA Program Description (Combined Licenses)

Regulatory Guides

Division 1 - Power Reactors

Division 2 - Research and Test Reactors

Division 3 - Fuels and Materials Facilities

Division 4 - Environmental and Siting

Division 5 - Materials and Plant Protection

Division 6 - Products

Division 7 - Transportation

Division 8 - Occupational Health

Division 9 - Antitrust and Financial Review

Division 10 - General

NRC Environmental and Siting (Division 4): Regulatory Guides 4.1 - 4.20

#	Title
4.1	Radiological Environmental Monitoring for Nuclear Power
4.2	Preparation of Environmental Reports for Nuclear Power Stations
4.2S1	Supplement 1 to Regulatory Guide 4.2, Preparation of Supplemental Environmental Reports for Applications To Renew Nuclear Power Plant Operating
4.3	Measurements of Radionuclides in the Environment, Analysis of I-131 in Milk (**Withdrawn**--See 41 FR 53870, 12/09/1976)
4.4	Reporting Procedure for Mathematical Models Selected To Predict Heated Effluent Dispersion in Natural Water Bodies
4.5	Measurements of Radionuclides in the Environment--Sampling and Analysis of Plutonium in Soil (**Withdrawn** -- See 74 FR 55074, October 26, 2009.)
4.6	Measurements of Radionuclides in the Environment-- Strontium-89 and Strontium-90 Analyses (**Withdrawn** -- See 74 FR 55074, October 26, 2009.)
4.7	General Site Suitability Criteria for Nuclear Power
4.8	Environmental Technical Specifications for Nuclear Power Plants (for Comment) (**Withdrawn** See 74 FR 21017, May 6, 2009.)
4.9	Preparation of Environmental Reports for Commercial Uranium Enrichment Facilities
4.10	Irreversible and Irretrievable Commitment of Material Resources (**Withdrawn**--See 42 FR 59436, 11/17/1977)
4.11	Terrestrial Environmental Studies for Nuclear Power Stations
4.12	(Not published)
4.13	Performance, Testing, and Procedural Specifications for Thermoluminescence Dosimetry: Environmental Applications
4.14	Radiological Effluent and Environmental Monitoring at Uranium Mills
4.15	Quality Assurance for Radiological Monitoring Programs (Inception through Normal Operations to License Termination) -- Effluent Streams and the Environment
4.16	Monitoring and Reporting Radioactivity in Releases of Radioactive Materials in Liquid and Gaseous Effluents from Nuclear Fuel Processing and Fabrication Plants and Uranium Hexafluoride Production
4.17	Standard Format and Content of Site Characterization Plans for High-Level-Waste Geologic Repositories
4.18	Standard Format and Content of Environmental Reports for Near-Surface Disposal of Radioactive Waste
4.19	Guidance for Selecting Sites for Near-Surface Disposal of Low-Level Radioactive Waste
4.20	Constraint on Releases of Airborne Radioactive Materials to the Environment for Licensees other than Power Reactors

Parties involved in Nuclear Quality

- NRC Commissioners
- NRC Organization and Staff Structure

- Nuclear Procurement Issues Committee (NUPIC)
  - All domestic U.S. nuclear utilities and several international members.
  - To improve supplier assurance processes through cooperative efforts while minimizing utility operations and maintenance and improving plan performance

- Nuclear Engineering Institute (NEI)
  - Policy organization for the nuclear technology industry
  - 350 members in 19 countries

- American Nuclear Society (ANS)
  - 11,500 member professional society

Nuclear Procurement Issues Committee (NUPIC)

- Conducts vendor assessments
- Results are shared among members
- NRC may accompany members of audit teams
- Focus on the NUPIC Checklist

- Items that NUPIC will focus on this year:
  - Dedication of commercial-grade software used in safety-related analysis per Appendix B, Criteria III
  - Internal Audit Effectiveness evaluating ability of vendor to self-identify problems
  - Counterfeit and fraudulent parts

- Commercial-grade =
- Commercial-grade dedication = a process by which a commercial-grade item (CGI) is designated for use as a basic component.

NRC's July 2003 Comparison to ISO 9001

- Identified lack in ISO 9001 in the areas of "regulatory impact & compliance"
- Identified missing requirements in ISO 9001
- NRC identified two approaches suitable for further development
  - specific controls for ISO 9001 certified suppliers during procurement and
  - using ISO 9001 certified suppliers for procuring commercial-grade items.

Evolution of Nuclear QA

(Faulkner/Wood DOE Environmental Management www.em.doe.gov)

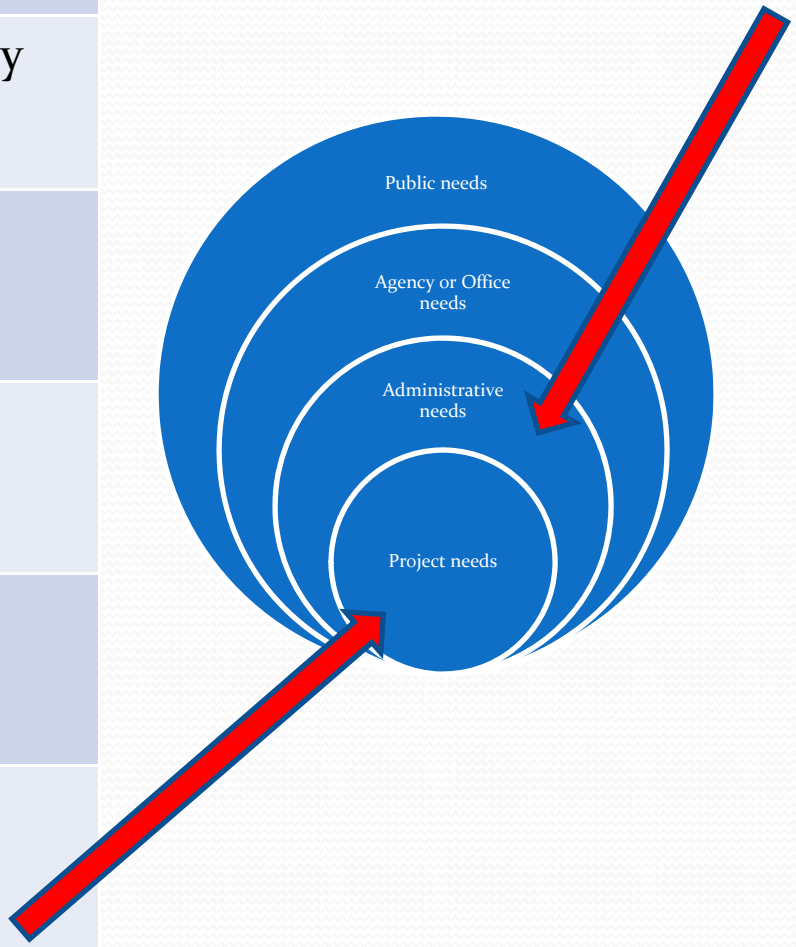
- 1954 AEC QC-1 QC for AEC weapons programs
- 1958 DOD Mil-Q-9858A Quality specifications
- 1962 NASA NPC 250-1 Quality standard
- 1964 AEC QRC-82 QC for AEC naval reactors
- 1965 ASME Section III QA for Nuclear Pressure Vessels
- 1970 AEC 10CFR50 Appendix B – QA Criteria
- 1971 ASME N45.2 Began QA Program development
- 1979 ASME NQA-1 Consolidated N45.2 program
- 1981 DOE 5700.6 DOE QA Policy
- 1983 ASME NQA-2 Consolidated NQA-2 QA methods
- 1987 ISO ISO 9000 Quality Management System
- 1990 ASME NQA-3 QA data standard
- 1994 DOE 10CFR830.120 Quality Assurance Requirements
- 1999 DOE Order 414.1A Replaced DOE Order 5700.6C

Exercise – building a nuclear-powered facility

1. Decide who will do what and how long it will take to build
2. Learn and understand construction methods and nuclear issues
3. Make detailed drawing what is to be built, get all the permits
4. Buy the right materials, and the nuclear reactor
5. Check delivered materials, store them securely, hire qualified workers.
6. Build the nuclear plant according to drawings; check workmanship
7. Keep eyes open to detect problems that occur and fix them
8. Maintain the permits and save the receipts
9. Step back periodically and evaluate overall progress
10. Ask the inspectors to look at the job

Environmental Measurement Discipline MATRIX

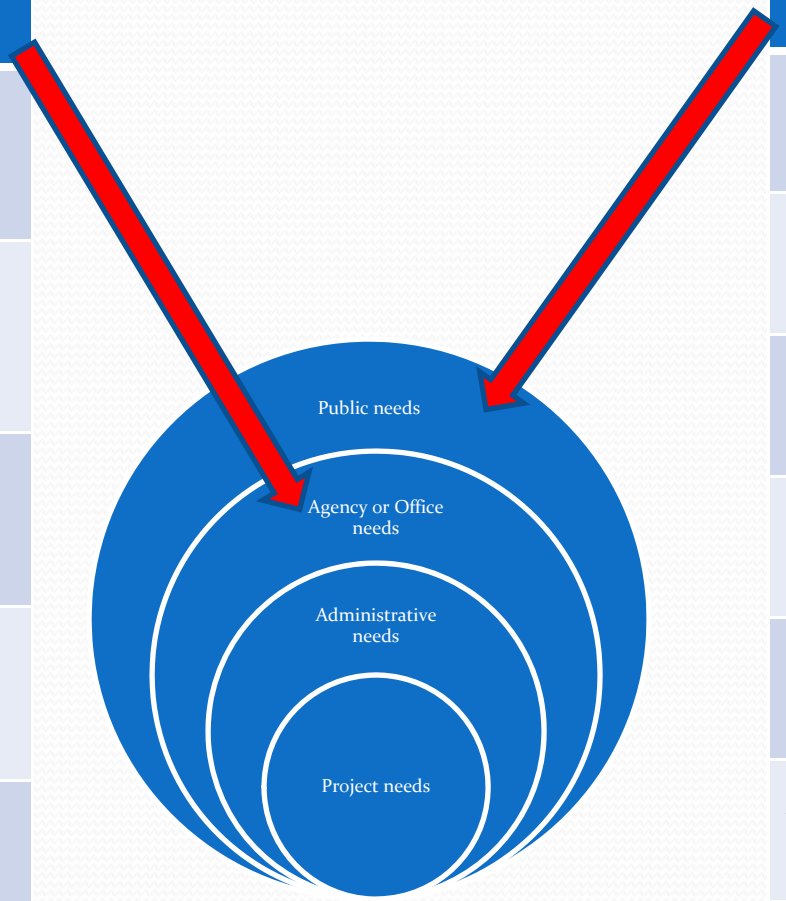
PROJECT
Project planning
Env. Technology Design
Sampling methodology
Analytical methodology
Assessment methodology
Information capture



ADMIN.
Conformity to planning requirements
Sampling standards
Analytical standards
Assessment standards
Information and data standards
Information technology standards
Environmental technology standards

Environmental Measurement Discipline MATRIX

OFFICE
Agency mission alignment
Fed Requirements Management Integrity
Fed Requirements IQGs
Fed Requirements FOIA
Fed Requirements FISMA
Fed Requirements



PUBLIC
Solution benefit
Transparency
Utility of information
Data provenance
Usability of data (secondary)
Access to information

ANALYSIS – Observations of NRC Quality Approach as a Model for Internal Control for Technical Operations

- Requirements narrowly focused on single industry
- Requirements focused on quality for safety
- Quality for measurements covers all measurements – both technical and environmental
- Quality criteria for information focus now on commercial grade software – not necessarily entire model for all information
- Quality criteria is externally focused – link to internal Agency quality may not be clear

CONCLUSION 1 – NRC strengths for Internal Controls for Technical Operations

- Agency approval at all major steps in the project
- Agency on-site oversight
- Formal vendor overview program
- Strong requirements for software related to safety
- Integration of quality and safety considerations

CONCLUSION 2 –

…… comparisons of Federal Quality Systems not easily found

OTHER AREAS TO EXPLORE:

- What are the basic categories of government services?
- What is the general approach to ensuring the quality of government services?
- What are all the sources of government information?
- What are the basic categories of that information?
- How can alignment of the quality management approach be strengthened?

March 28, 2011 EPA Policy to Assure Competency of Laboratories, Field Sampling, and Other Organizations Generating Environmental Measurement Data under Agency-Funded Acquisitions

- Organizations performing environmental analysis for the Agency shall **demonstrate their qualifications** in the fields of analyses to be conducted, prior to performing such analyses.

- Where accreditation or certification is available for those fields of analysis, organizations **may submit documentation of existing accreditations or certifications.**

- **Accreditation/certification** granted by an organization that accredits environmental data operations to an international consensus standard, or a state accreditation or certification program acceptable to EPA, or the contracted laboratory's participation in the EPA Contract Laboratory Program for those fields or analyses, **shall be valid at the time of award and must be sustained through the life of the period of performance**.

- If accreditation / certification is **suspended or revoked** at any time during the life of the period of performance, the **EPA project officer must be notified** immediately to ensure any potential impact on the scope of work being performed is addressed accordingly.

Discussion And Questions ??????

QUESTIONS?

CONTACT INFORMATION

Jeffrey Worthington - EPA

202-566-0995

worthington.jeffrey@epa.gov